# MECLIZINE HCL - meclizine hydrochloride tablet Bryant Ranch Prepack

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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Travel Sickness

Active Ingredient (in each tablet) Meclizine HCl 25 mg

**Purpose** 

**Antiemetic** 

#### Uses

prevents and treats nausea, vomiting, or dizziness due to motion sickness

#### **WARNINGS**

#### Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

#### **Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers

### When using this product

- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives & tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- take dose one hour before travel starts
- tablets can be chewed or swallowed whole with water
- adults & children 12 years and over: 1-2 tablets once daily children under 12 years: ask a doctor

#### Other Information

- phenylketonurics: each tablet contains: phenylalanine 0.28 mg
- store at room temperature 15°-30°C (59°-86°F)

#### **Inactive Ingredients**

aspartame, compressible sugar, croscarmellose sodium, dextrose, FD&C red # 40(Al-lake), magnesium stearate, microcrystalline cellulose, raspberry flavor

#### **Questions or Comments**

Call **1-800-645-2158**, 9 am – 5 pm ET, Monday - Friday

## TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Rugby® Duluth, Georgia 30097

**Meclizine 25MG Chewable** 



#### **MECLIZINE HCL**

meclizine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63629-4008(NDC:0536-3990)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
ASPARTAME (UNII: Z0H242BBR1)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
SUCROSE (UNII: C151H8 M554)		

DEXTROSE (UNII: IY9XDZ35W2)

FD&C RED NO. 40 (UNII: WZB9127XOA)

RASPBERRY (UNII: 4N14V5R27W)

Product Characteristics			
Color	RED	Score	2 pieces
Shape	ROUND	Size	8 mm
Flavor	RASPBERRY	Imprint Code	AP;115
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-4008-1	30 in 1 BOTTLE		
2	NDC:63629-4008-2	20 in 1 BOTTLE		
3	NDC:63629-4008-3	25 in 1 BOTTLE		
4	NDC:63629-4008-4	40 in 1 BOTTLE		
5	NDC:63629-4008-5	60 in 1 BOTTLE		
6	NDC:63629-4008-6	90 in 1 BOTTLE		
7	NDC:63629-4008-7	8 in 1 BOTTLE		
8	NDC:63629-4008-8	14 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part336	07/22/2008		

## Labeler - Bryant Ranch Prepack (171714327)

### Registrant - Bryant Ranch Prepack (171714327)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bryant Ranch Prepack		171714327	REPACK(63629-4008), RELABEL(63629-4008)	

Revised: 2/2013 Bryant Ranch Prepack